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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,059	09/23/2003	Victor Schoenle	10527-477001	2738
26161	7590	11/02/2006	EXAMINER	
FISH & RICHARDSON PC			AUGHENBAUGH, WALTER	
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1772

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/669,059

Applicant(s)

SCHOENLE ET AL.

Examiner

Walter B. Aughenbaugh

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2006 and 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 74,76-84,86-92,94-104,106-118 and 120-139 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 74,76-84,86-92,94-104,106-118 and 120-139 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Acknowledgement of Applicant's Amendments***

1. The amendments made in claims 74, 78-80, 82-84, 88, 89, 91, 92, 96-99, 101-104, 108-112, 114-118, 122-125 and 127-139 in the Amendment filed on June 16, 2006 (Amdt. B) have been received and considered by Examiner.

### ***WITHDRAWN REJECTIONS***

2. The 35 U.S.C. 112, second paragraph, rejection of claims 74, 80, 84, 89, 92, 99, 104, 112, 118 and 125 made of record in paragraph 11 of the previous Office Action mailed April 6, 2006 has been withdrawn due to Applicant's amendment in claims 74, 80, 84, 89, 92, 99, 104, 112, 118 and 125 in Amdt. B.

3. The 35 U.S.C. 102 rejection of claims 84, 86, 88, 89 and 91 that was repeated in paragraph 7 of the previous Office Action mailed April 6, 2006 has been withdrawn due to Applicant's replacement of "polyester" with --polyamide-- in claims 84, 88, 89 and 91 in Amdt. B.

4. The 35 U.S.C. 102 rejection made of record in paragraph 12 of the previous Office Action mailed April 6, 2006 has been withdrawn due to Applicant's replacement of "polyester" with --polyamide-- in the pertinent claims in Amdt. B.

5. The 35 U.S.C. 103 rejection made of record in paragraph 13 of the previous Office Action mailed April 6, 2006 has been withdrawn due to Applicant's replacement of "polyester" with --polyamide-- in the pertinent claims in Amdt. B.

***NEW REJECTIONS***

***Claim Rejections - 35 USC § 112***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 74-139 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In regard to claims 74-139, the specification does not indicate which polyamides listed in the paragraph bridging pages 12 and 13 of the specification satisfy which of the various mechanical property minima (equivalently, minimum values) listed on pages 2-5 of the specification and claimed.

In further regard to claims 92-103, 111, 117, Applicant does not explain in the specification how the claimed “load at break ratio” is determined. The “load at break ratio” is mentioned only on pages 2 and 5 of the specification. While the method of determining all other claimed properties are disclosed on pages 10-12, 14, 15 and 24-26, the method of determining the claimed “load at break ratio” is not disclosed.

***Claim Rejections - 35 USC § 102***

8. Claims 74, 76-78, 80-82, 104, 106-109, 112-115, 118, 120-123 and 125-128 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk et al. (USPN 6,110,142).

In regard to claim 74, Pinchuk et al. teach a component (catheter, item 21, which includes balloon, item 26, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36, which is tube-

Art Unit: 1772

shaped) of a medical device, where the component comprises a polyamide having a tensile strength of between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 21,000 psi.

In regard to claim 80, Pinchuk et al. teach a tube-shaped portion (balloon, items 33 and 34, Fig. 1, col. 5, lines 6-9) of a catheter (item 21, Fig. 1, col. 5, lines 14-16) where the tube-shaped portion comprises a polyamide having a tensile strength of between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 21,000 psi.

In regard to claims 104 and 108, Pinchuk et al. teach a component (catheter, item 21, which includes balloon, item 26, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36, which is tube-shaped) of a medical device, where the component comprises a polyamide having a hoop expansion ratio, which corresponds to the hoop stress ratio as claimed, of 3.3, 3.7 or 4.9 (col. 13, lines 14-19).

In regard to claims 112 and 114, Pinchuk et al. teach a tube-shaped portion (balloon, items 33 and 34, Fig. 1, col. 5, lines 6-9) of a catheter (item 21, Fig. 1, col. 5, lines 14-16) where the tube-shaped portion comprises a polyamide having a hoop expansion ratio, which corresponds to the hoop stress ratio as claimed, of 3.3, 3.7 or 4.9 (col. 13, lines 14-19).

In regard to claims 118 and 122, Pinchuk et al. teach a component (catheter, item 21, which includes balloon, item 26, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36, which is tube-shaped) of a medical device, where the component comprises a polyamide having a post buckle fracture tensile strength of between about 15,000 and about 35,000 psi (col. 11,

Art Unit: 1772

lines 17-21), a range that overlaps with the claimed post buckle fracture tensile strength values of at least about 6500 psi and at least about 8000 psi.

In regard to claim 125 and 127, Pinchuk et al. teach a tube-shaped portion (balloon, items 33 and 34, Fig. 1, col. 5, lines 6-9) of a catheter (item 21, Fig. 1, col. 5, lines 14-16) where the tube-shaped portion comprises a polyamide having a post buckle fracture tensile strength of between about 15,000 and about 35,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed post buckle fracture tensile strength values of at least about 6500 psi and at least about 8000 psi.

In regard to claims 76, 106 and 120, Pinchuk et al. teach that the component is tube-shaped and a catheter (item 21, Fig. 1, col. 5, lines 14-16 and col. 1, lines 24-27 and 33-36).

In regard to claims 77, 81, 107, 113, 121 and 126, Pinchuk et al. teach that the balloon can be coated with lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that the balloon comprises a first layer (the polyamide layer of Pinchuk et al.) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layer necessarily have different flexibilities).

In regard to claims 78 and 82, Pinchuk et al. teach that the tensile strength is between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 22,500 psi.

In regard to claims 109, 115, 123 and 128, Pinchuk et al. teach that the tensile strength is between about 20,000 and about 32,000 psi (col. 11, lines 17-21), a range that overlaps with the claimed tensile strength values of at least about 21,000 psi.

Art Unit: 1772

9. Claims 84, 86, 88, 89 and 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Sahatjian et al. (USPN 5,306,246).

In regard to claims 84 and 88, Sahatjian et al. teach a component (catheter including balloon, item 4, Fig. 2, item 4 shown but unlabeled in Fig. 1, which is tube-shaped) of a medical device (col. 2, lines 32-35), where the component comprises a polyamide having a hoop stress greater than about 36,000 psi (col. 1, lines 50-51, col. 7, lines 38-48 and col. 8, lines 16-18).

In regard to claim 86, Sahatjian et al. teach that the component is a catheter (col. 2, lines 32-35 and Fig. 1).

In regard to claims 89 and 91, Sahatjian et al. teach a tube-shaped portion (balloon, item 4, Fig. 2, shown but unlabeled in Fig. 1 and col. 2, lines 32-35 and 58-61) of a catheter (col. 2, lines 32-35) where the tube-shaped portion has a hoop stress greater than about 36,000 psi (col. 1, lines 50-51).

#### ***Claim Rejections - 35 USC § 103***

10. Claims 79, 83, 110, 116, 124 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. (USPN 6,110,142) in view of Sahatjian et al. (USPN 5,306,246).

Pinchuk et al. teach the component and tube-shaped portion of a catheter as discussed above. Pinchuk et al. teach that the polymer of the balloon is a polyamide (col. 11, lines 17-21).

Pinchuk et al. fail to teach that the balloon has a hoop stress of at least about 3300 psi.

Sahatjian et al. teach a balloon (col. 2, lines 32-35) comprising polyamide (col. 3, lines 48-62) where the material comprising polyamide has a hoop stress greater than about 36,000 psi (col. 1, lines 50-51, col. 7, lines 38-48 and col. 8, lines 16-18). Therefore, one of ordinary skill in

Art Unit: 1772

the art would have recognized to have used the material comprising polyamide that has a hoop stress greater than about 36,000 psi of the balloon of Sahatjian et al. as the polyamide of the balloon of Pinchuk et al. since a material that has a hoop stress greater than about 36,000 psi is a well known suitable material for use as the material of a catheter balloon as taught by Sahatjian et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the material comprising polyamide that has a hoop stress greater than about 36,000 psi of the balloon of Sahatjian et al. as the polyamide of the balloon of Pinchuk et al. since a material that has a hoop stress greater than about 36,000 psi is a well known suitable material for use as the material of a catheter balloon as taught by Sahatjian et al.

11. Claims 87 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian et al. (USPN 5,306,246) in view of Pinchuk et al. (USPN 6,110,142).

Sahatjian et al. teach the balloon as discussed above. Sahatjian et al. teach that the balloon (col. 2, lines 32-35) comprises polyamide (col. 3, lines 48-62)

Sahatjian et al. fail to teach that the balloon comprises a first layer and a second layer where the first layer has a different flexibility from that of the second layer.

Pinchuk et al., however, teach that balloons can be coated with non-thrombogenic lubricants such as polyvinyl pyrrolidone (col. 11, lines 6-9) and therefore teach that balloons can comprise a first layer (the polyamide layer) and a second layer (the polyvinyl pyrrolidone coating layer of Pinchuk et al.) where the first layer has a different flexibility from the second layer (since the two layers consist of different materials, the two layers necessarily have different flexibilities). Therefore, one of ordinary skill in the art would have recognized to have coated the



Art Unit: 1772

balloon of Sahatjian et al. with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the balloon of Sahatjian et al. with a non-thrombogenic lubricant such as polyvinyl pyrrolidone since it is well known to coat balloons with non-thrombogenic lubricants in order to increase the lubricity of the balloons as taught by Pinchuk et al.

***Response to Arguments***

12. Applicant's arguments presented on pages 10-12 of Amdt. B regarding the 35 U.S.C. 112, first paragraph, rejection of claims 74-129 have been fully considered but are not persuasive.

Applicant's statements in the second paragraph under the "Claim rejections..." heading on page 10 of Amdt. B regarding the "exemplary processes" disclosed in the specification do not address the basis for the rejection of record. The specification does not indicate which polyamides listed in the paragraph bridging pages 12 and 13 of the specification satisfy which of the various mechanical property minima (equivalently, minimum values) listed on pages 2-5 of the specification and claimed.

Applicant's arguments regarding the polyamides disclosed in the specification on pages 10-11 of Amdt. B are not persuasive because "31,659 psi" is not "about 21,000 psi", "5,115 psi" is not "about 3300 psi", and "13,642 psi" is not "about 6500 psi", and Applicant has not addressed the other claimed mechanical property minima in the arguments presented in Amdt. B.

In regard to the additional basis for rejection of claims 92-103, 111, 117, Applicant does

Art Unit: 1772

not explain in the specification how the claimed “load at break ratio” is determined. The “load at break ratio” is mentioned only on pages 2 and 5 of the specification. While the method of determining all other claimed properties are disclosed on pages 10-12, 14, 15 and 24-26, the method of determining the claimed “load at break ratio” is not disclosed. Applicant’s statement that “Applicants believe that, after reading the application, one skilled in the art would understand what is meant by this term” (third full paragraph, page 11 of After Final Amdt.) is unsupported. Applicant’s statement under the second block quote on page 12 of After Final Amdt. that “it is apparent that one skilled in the art would understand... extruded tube)” is unsupported.

13. Applicant’s argument presented on page 12 of Amdt. B regarding the 35 U.S.C. 112, second paragraph, rejection of claims 74, 80, 84, 89, 92, 99, 104, 112, 118 and 125 made of record in paragraph 11 of the previous Office Action mailed April 6, 2006 is moot since the rejection has been withdrawn due to Applicant’s amendment in claims 74, 80, 84, 89, 92, 99, 104, 112, 118 and 125 in Amdt. B.

14. Applicant’s arguments presented on pages 12-13 of Amdt. B regarding the 35 U.S.C. 102 rejection of claims 84, 86, 88, 89 and 91 have been fully considered but are not persuasive.

Applicant argues that “Sahatjian does not disclose or suggest forming his dilation balloon out of a polyamide”, but, in regard to claims 84 and 88, Sahatjian et al. teach a component (catheter including balloon, item 4, Fig. 2, item 4 shown but unlabeled in Fig. 1, which is tube-shaped) of a medical device (col. 2, lines 32-35), where the component comprises a polyamide having a hoop stress greater than about 36,000 psi (col. 1, lines 50-51, col. 7, lines 38-48 and col. 8, lines 16-18).

Art Unit: 1772

15. Applicant's arguments presented on page 13 of Amdt. B regarding the 35 U.S.C. 102 rejection based on Robinson is moot due to the withdrawal of this rejection in this Office Action.

16. Applicant's arguments presented on page 13 of Amdt. B regarding the 35 U.S.C. 103 rejection based on Robinson is moot due to the withdrawal of this rejection in this Office Action.

17. Applicant's arguments presented on pages 13-14 of Amdt. B regarding the 35 U.S.C. 103 rejection of claims 87 and 90 have been fully considered but are not persuasive.

Applicant argues that "Sahatjian does not disclose articles including a polyamide", but Sahatjian et al. teach a component that comprises a polyamide having a hoop stress greater than about 36,000 psi (col. 1, lines 50-51, col. 7, lines 38-48 and col. 8, lines 16-18). Applicant argues that there is no motivation to combine the references since Sahatjian et al. do not teach "articles including a polyamide", but Sahatjian et al. teach a component that comprises a polyamide having a hoop stress greater than about 36,000 psi (col. 1, lines 50-51, col. 7, lines 38-48 and col. 8, lines 16-18).

### ***Conclusion***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh  
10/29/06

WBA



JENNIFER MCNEIL  
SUPERVISORY PATENT EXAMINER

10/30/06